

REMARKS

This amendment responds to the Office Action which was mailed on October 8, 2003. In the claims, Claims 63-74 have been canceled. In light of the amendment and the remarks set forth below it is respectfully submitted that the application is in condition for allowance. Applicant requests a favorable reconsideration of the application in light of the amendment and the remarks set forth below which constitute a full and complete response to the outstanding Office Action.

In the Office Action, Claims 63-74 were rejected under 35 U.S.C. § 112, as failing to comply with the written description requirement and providing enablement. These claims have now been canceled.

Claims 1, 9, 13, 21, 25, 33, 37, 45, and 51-53 were rejected under 35 U.S.C. § 102(b) as being anticipated by Tomalia et al., U.S. Pat. No. 5,338,532. Although Tomalia teaches Starburst or polyamidoamine conjugates, polyethyleneimines and polyamidoamine dendrimers, and in general terms discloses useful surface functional groups, it is respectfully submitted that Tomalia does not anticipate applicant's claimed invention and that rejection of these claims as anticipated is untenable and should be withdrawn.

Under well-established court decisions, anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. These elements must either be expressly disclosed by the prior art reference or be inherent, and must be arranged as in the claim. For anticipation, there must be no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary

skill in the art. Therefore, the absence of any claimed element from the cited reference negates anticipation.

Claim 1 recites in pertinent part "a molecularly compact polymer-ligand conjugate capable of self-orienting on a surface, wherein said molecularly compact polymer comprises a fifth-generation (G5) polyamidoamine dendrimer having surface functional groups, wherein said surface functional groups comprise about 75% hydroxyl groups and about 25% primary amine groups..." . Applicants have discovered polymer-ligand conjugates which are particularly useful because they are self-orienting. Critical to this self-orientation feature is the fact that specific surface functional groups have been combined with specific dendrimers (specific as to both generation and chemical composition of dendrimer) to obtain self-orientation.

It is clear that Tomalia does not expressly or inherently disclose or teach the compact polymers as claimed by applicant. Applicant's claim 1, for example, recites a fifth generation polyamidoamine dendrimer having 75% hydroxyl and 25% primary amine surface functional groups. In contrast, Tomalia provides a very broad and general teaching of starburst polyamidoamine dendrimers having surface functional groups selected from a long list of groups (See column 24, lines 10-24). Although this long list of possible surface functional groups includes hydroxyl and amine groups, it can not be disputed that Tomalia does not disclose the unique polymer-ligand conjugates which applicants are claiming. For example, Tomalia does not expressly or inherently disclose the fifth generation (G5) polyamidoamine dendrimer having about 75% hydroxyl and 25% primary amine surface functional groups as recited in Claim 1. Nor does Tomalia disclose either expressly or inherently the sixth generation (G6) to tenth generation (G10)

polyamidoamine dendrimer having greater than 75% hydroxyl and less than 25% primary amine surface functional groups of Claim 13. Nor does Tomalia disclose either expressly or inherently the first generation (G1) to second generation (G2) polyamidoamine dendrimer having less than about 20% hydroxyl groups and greater than about 80% primary amine surface functional groups of Claim 25. Nor does Tomalia disclose either expressly or inherently third generation (G3) to fourth generation (G4) polyamidoamine dendrimer having less than about 50% hydroxyl and greater than about 50% primary amine surface functional groups of Claim 37. Nor does Tomalia teach or disclose either expressly or inherently the fifth-generation (G5) polyamidoamine dendrimer having about 75% hydroxyl and 25% primary amine surface functional groups of Claim 49. Nor does Tomalia teach or disclose either expressly or inherently the polyethyleneimine dendrigraft polymer of Claim 51, or the specific generations of the polyethyleneimine dendrigraft polymer of Claims 52-53.

The Office Action states that regarding the percentage of hydroxyl functional groups, routine experimentation can be done to accomplish such percentages of the hydroxyl functional groups. First of all, applicant strongly disagrees that the unique combinations of specific generations of polymers with specific percentages of hydroxyl functional groups can be obtained through routine experimentation. Furthermore, applicant's invention comprises a combination of specific percentages of both hydroxyl *and* primary amine surface functional groups. As stated above, Tomalia does not teach or even suggest the specific combinations of polymers and surface functional groups which applicant has discovered have unique self-orienting characteristics. Finally, anticipation under § 102 requires the express disclosure of applicant's claimed invention without any

reliance upon further experimentation. Therefore, it is respectfully submitted that rejection of Claims 1, 13, 25, 37, 51, and their dependent Claims 9, 21, 33, 45, and 52-53 which are further limiting thereto, under § 102(b) is untenable and should be withdrawn.

Claims 2-3, 14-15, 26-27, and 38-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tomalia in view of Klimash et al., U.S. Pat. No. 6,020,457. Of course, it is well-established law that in order for a claimed invention to be found obvious all of the claim elements and limitations must be collectively taught by the combined teachings of the cited references, i.e., the prior art must teach every element and/or limitation of the claimed invention, and provide some suggestion or motivation for combining the references to produce the claimed invention. It is respectfully submitted that the combined teachings of Tomalia and Klimash do not teach, disclose or even suggest applicant's claimed invention.

More particularly, Klimash teaches dendritic polymers having disulfide functional groups which form sulfhydryl groups upon being subjected to reducing agents. Klimash teaches using quartz as the surface for binding polymer and coupling dendritic polymer to antibody fragments. Klimash teaches that these compounds are useful for detecting mass buildup on the surface of electrodes. In addition, the Klimash polymers can have different surface functional groups such as amines.

However, the combined teachings of Tomalia (as discussed in the foregoing) and Klimash do not collectively teach the limitations of the applicant's claimed invention. Applicants have discovered that unique combinations of specific generation dendrimer polymers and surface functional groups provide unique self-orienting properties. For example, Claim 1 recites a fifth generation polyamidoamine dendrimer polymer having

about 75% hydroxyl and 25% primary amine surface functional groups. This dendrimer polymer is used in a polymer-ligand conjugate having desirable self-orienting properties. The combined teachings of Tomalia and Klimash do not teach or even suggest such a specific dendrimer polymer for use as a polymer-ligand conjugate. Klimash does not teach such a polymer and, as discussed in the foregoing, although Tomalia generally discloses polyamidoamine dendrimer polymers and the fact that many different surface functional groups can be used with said dendrimer, it does not teach or even suggest applicant's claimed invention comprising a fifth-generation polyamidoamine dendrimer having a combination of 75% hydroxyl and 25% primary amine surface functional groups as recited in Claim 1. Similarly, the unique and specific polymer-ligand conjugates of Claims 13, 25, 37, 49, and 51-53 are not taught, disclosed, or suggested by the combined teachings of the Tomalia and Klimash references. Each of these polymers also comprises a specific generation polymer having a specific combination of hydroxyl and primary amine surface functional groups which produces desirable self-orienting properties. It is respectfully submitted that the combined disclosures of Tomalia and Klimash do not teach applicant's claim limitations, and that rejection under § 103(a) should be withdrawn.

Claims 3-6, 15-18, 27-30, 39-42, 49, and 54-57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tomalia in view of Hunter et al., U.S. Pat. No. 5,581,777. Hunter was relied on to teach ligand-dendrimer conjugates having colloidal particles and size ranges. Here again, the collective teachings of Tomalia and Hunter do not teach applicant's claim limitations. Tomalia has been discussed at length above, and it is clear that Tomalia does not teach applicant's claimed invention comprising specific

generation dendrimer polymers having specific percentages of hydroxyl and primary amine surface functional groups. Hunter also fails to teach these claim limitations. It is respectfully submitted, therefore, that applicant's claims are patentable over the prior art cited and in condition for allowance. Respectfully request that the rejection under § 103(a) be withdrawn.

Claims 7, 8, 19, 20, 31, 32, 43, 44, 58, and 59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tomalia in view of Hunter and further in view of Keen, U.S. Pat. No. 6,060,327. Keen was relied on to teach inorganic particles such as cadmium selenide and cadmium sulfide as substrates attached to conductive polymers. Here again, the collective teachings of Tomalia, Hunter and Keen do not teach applicant's claim limitations. Tomalia has been discussed at length above, and it is clear that Tomalia does not teach applicant's claimed invention comprising specific generation dendrimer polymers having specific percentages of hydroxyl and primary amine surface functional groups. Hunter and Keen also fails to teach these claim limitations. It is respectfully submitted, therefore, that applicant's claims are patentable over the prior art cited and in condition for allowance. Respectfully request that the rejection under § 103(a) be withdrawn.

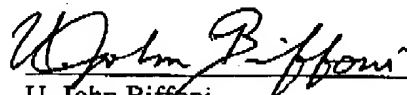
Claims 10-12, 22-24, 34-36, 46-48, 50, and 60-62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tomalia in view of Moll, III et al., U.S. Pat. No. 6,121,056, and further in view of May et al., U.S. Pat. No. 5,656,503. Moll was relied on to teach methods and articles of manufacture for conducting specific binding assays to determine the concentration or presence of at least one analyte in a sample. May was relied on to teach an analytical test device comprising a moisture impervious casing

having a nitrocellulose strip which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier. Here again, the combined teachings of Tomalia, Moll, and May do not teach applicant's claim limitations. Tomalia has been discussed at length above, and it is clear that Tomalia does not teach applicant's claimed invention comprising specific generation dendrimer polymers having specific percentages of hydroxyl and primary amine surface functional groups. Moll and May also fails to teach these claim limitations. Therefore, it is respectfully submitted that applicant's claims are patentable over the prior art cited and in condition for allowance. Respectfully request that the rejection under § 103(a) be withdrawn.

In summary, Claims 63-74 have been canceled and Claims 1-62 remain in the case. Based on the foregoing arguments, Claims 1-62 should not be considered anticipated or obvious over the prior art cited. Accordingly, it is respectfully submitted that these claims are patentable and in condition for allowance. Early reconsideration and withdrawal of the rejections is earnestly solicited, as is allowance of the claimed subject matter.

Respectfully submitted,

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DATE


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